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WARNER-LAMBERT COMPANY			NOLAN, JASON MICHAEL	
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ANN ARBOR, MI 48105			PAPER NUMBER	

1626

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Please find below and/or attached an Office communication concerning this application or proceeding.



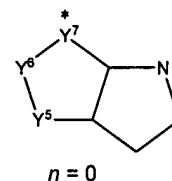
**DETAILED ACTION**

**Claims 1-12** are currently pending in the instant application and are subject to a restriction requirement.

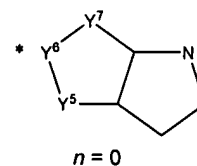
***Election/Restrictions***

The Markush group set forth in the claims includes both independent and distinct inventions, as well as a plurality of patentably distinct compounds (or species) within each invention. For these reasons provided below, restriction to one of the following inventions is required under 35 U.S.C. 121, wherein a Group is a set of patentably distinct inventions of a broad statutory category (e.g. compounds, methods of making, methods of using, etc):

- I. **Claims 1-10**, drawn to compounds and compositions of Formula I, wherein the variables outlined in Claim 1 are as described except for the following requirements:  $n = 0$ ;  $Y^5$ ,  $Y^6$ , &  $Y^7$  are each  $C(R^{10})R^{10w}$  or  $Y^7$  may be selected from O, S, S(O), S(O)<sub>2</sub>, and NR<sup>5</sup> and  $Y^5$  and  $Y^6$  are each  $C(R^{10})R^{10w}$ .

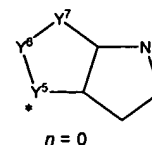


- II. **Claims 1-10**, drawn to compounds and compositions of Formula I, wherein the variables outlined in Claim 1 are as described except for the following requirements:  $n = 0$ ;  $Y^5$ ,  $Y^6$ , &  $Y^7$  are each  $C(R^{10})R^{10w}$  or  $Y^6$  may be selected from O, S, S(O), S(O)<sub>2</sub>, and NR<sup>5</sup> and  $Y^7$  and  $Y^5$  are each  $C(R^{10})R^{10w}$ .

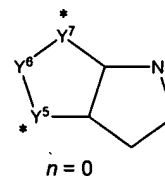


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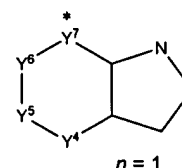
- III. **Claims 1-10**, drawn to compounds and compositions of Formula I, wherein the variables outlined in Claim 1 are as described except for the following requirements:  $n = 0$ ;  $Y^5$ ,  $Y^6$ , &  $Y^7$  are each  $C(R^{10})R^{10w}$  or  $Y^5$  may be selected from O, S, S(O), S(O)<sub>2</sub>, and NR<sup>5</sup> and  $Y^7$  and  $Y^6$  are each  $C(R^{10})R^{10w}$ .



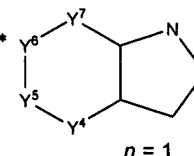
- IV. **Claims 1-10**, drawn to compounds and compositions of Formula I, wherein the variables outlined in Claim 1 are as described except for the following requirements:  $n = 0$ ;  $Y^7$  and  $Y^5$  may be selected from O, S, S(O), S(O)<sub>2</sub>, and NR<sup>5</sup> and  $Y^6$  is  $C(R^{10})R^{10w}$ .



- V. **Claims 1-10**, drawn to compounds and compositions of Formula I, wherein the variables outlined in Claim 1 are as described except for the following requirements:  $n = 1$ ;  $Y^4$ ,  $Y^5$ ,  $Y^6$ , &  $Y^7$  are each  $C(R^{10})R^{10w}$  or  $Y^7$  may be selected from O, S, S(O), S(O)<sub>2</sub>, and NR<sup>5</sup> and  $Y^4$ ,  $Y^5$  and  $Y^6$  are each  $C(R^{10})R^{10w}$ .



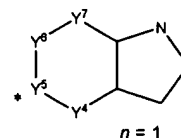
- VI. **Claims 1-10**, drawn to compounds and compositions of Formula I, wherein the variables outlined in Claim 1 are as described except for the following requirements:  $n = 1$ ;  $Y^4$ ,  $Y^5$ ,  $Y^6$ , &  $Y^7$  are each  $C(R^{10})R^{10w}$  or  $Y^6$  may be selected from O, S, S(O), S(O)<sub>2</sub>, and NR<sup>5</sup> and  $Y^4$ ,  $Y^5$  and  $Y^7$  are each  $C(R^{10})R^{10w}$ .



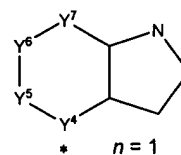
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VII. **Claims 1-10**, drawn to compounds and compositions of Formula I,

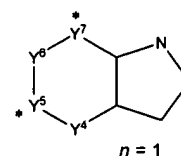
wherein the variables outlined in Claim 1 are as described except

for the following requirements:  $n = 1$ ;  $Y^4$ ,  $Y^5$ ,  $Y^6$ , &  $Y^7$  are each $C(R^{10})R^{10w}$  or  $Y^5$  may be selected from O, S, S(O), S(O)<sub>2</sub>, and NR<sup>5</sup>and  $Y^4$ ,  $Y^6$  and  $Y^7$  are each  $C(R^{10})R^{10w}$ .VIII. **Claims 1-10**, drawn to compounds and compositions of Formula I,

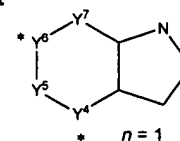
wherein the variables outlined in Claim 1 are as described except

for the following requirements:  $n = 1$ ;  $Y^4$ ,  $Y^5$ ,  $Y^6$ , &  $Y^7$  are each $C(R^{10})R^{10w}$  or  $Y^4$  may be selected from O, S, S(O), S(O)<sub>2</sub>, and NR<sup>5</sup>and  $Y^5$ ,  $Y^6$  and  $Y^7$  are each  $C(R^{10})R^{10w}$ .IX. **Claims 1-10**, drawn to compounds and compositions of Formula I,

wherein the variables outlined in Claim 1 are as described except

for the following requirements:  $n = 1$ ;  $Y^4$ ,  $Y^5$ ,  $Y^6$ , &  $Y^7$  are each $C(R^{10})R^{10w}$  or  $Y^7$  and  $Y^5$  may be selected from O, S, S(O), S(O)<sub>2</sub>,and NR<sup>5</sup> and  $Y^6$  and  $Y^4$  are each  $C(R^{10})R^{10w}$ .X. **Claims 1-10**, drawn to compounds and compositions of Formula I,

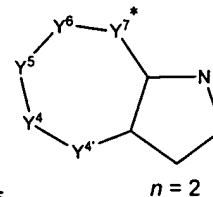
wherein the variables outlined in Claim 1 are as described except

for the following requirements:  $n = 1$ ;  $Y^4$ ,  $Y^5$ ,  $Y^6$ , &  $Y^7$  are each

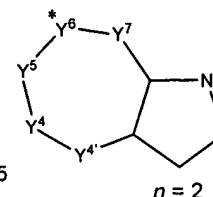
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$C(R^{10})R^{10w}$  or  $Y^6$  and  $Y^4$  may be selected from O, S, S(O), S(O)<sub>2</sub>,  
and NR<sup>5</sup> and  $Y^5$  and  $Y^7$  are each  $C(R^{10})R^{10w}$ .

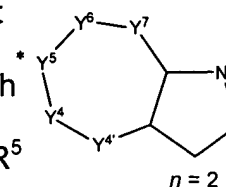
- XI. **Claims 1-10**, drawn to compounds and compositions of Formula I,  
wherein the variables outlined in Claim 1 are as described except  
for the following requirements:  $n = 2$ ;  $Y^{4'}$ ,  $Y^4$ ,  $Y^5$ ,  $Y^6$ , &  $Y^7$  are each  
 $C(R^{10})R^{10w}$  or  $Y^7$  may be selected from O, S, S(O), S(O)<sub>2</sub>, and NR<sup>5</sup>  
and  $Y^{4'}$ ,  $Y^4$ ,  $Y^5$  and  $Y^6$  are each  $C(R^{10})R^{10w}$ .



- XII. **Claims 1-10**, drawn to compounds and compositions of Formula I,  
wherein the variables outlined in Claim 1 are as described except  
for the following requirements:  $n = 2$ ;  $Y^{4'}$ ,  $Y^4$ ,  $Y^5$ ,  $Y^6$ , &  $Y^7$  are each  
 $C(R^{10})R^{10w}$  or  $Y^6$  may be selected from O, S, S(O), S(O)<sub>2</sub>, and NR<sup>5</sup>  
and  $Y^{4'}$ ,  $Y^4$ ,  $Y^5$  and  $Y^7$  are each  $C(R^{10})R^{10w}$ .



- XIII. **Claims 1-10**, drawn to compounds and compositions of Formula I,  
wherein the variables outlined in Claim 1 are as described except  
for the following requirements:  $n = 2$ ;  $Y^{4'}$ ,  $Y^4$ ,  $Y^5$ ,  $Y^6$ , &  $Y^7$  are each  
 $C(R^{10})R^{10w}$  or  $Y^5$  may be selected from O, S, S(O), S(O)<sub>2</sub>, and NR<sup>5</sup>  
and  $Y^{4'}$ ,  $Y^4$ ,  $Y^6$  and  $Y^7$  are each  $C(R^{10})R^{10w}$ .



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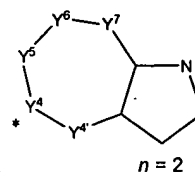
XIV. **Claims 1-10**, drawn to compounds and compositions of Formula I,

wherein the variables outlined in Claim 1 are as described except

for the following requirements:  $n = 2$ ;  $Y^{4'}$ ,  $Y^4$ ,  $Y^5$ ,  $Y^6$ , &  $Y^7$  are each

$C(R^{10})R^{10w}$  or  $Y^4$  may be selected from O, S, S(O), S(O)<sub>2</sub>, and NR<sup>5</sup>

and  $Y^{4'}$ ,  $Y^5$ ,  $Y^6$  and  $Y^7$  are each  $C(R^{10})R^{10w}$ .



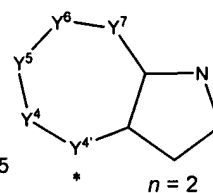
XV. **Claims 1-10**, drawn to compounds and compositions of Formula I,

wherein the variables outlined in Claim 1 are as described except

for the following requirements:  $n = 2$ ;  $Y^{4'}$ ,  $Y^4$ ,  $Y^5$ ,  $Y^6$ , &  $Y^7$  are each

$C(R^{10})R^{10w}$  or  $Y^{4'}$  may be selected from O, S, S(O), S(O)<sub>2</sub>, and NR<sup>5</sup>

and  $Y^4$ ,  $Y^5$ ,  $Y^6$  and  $Y^7$  are each  $C(R^{10})R^{10w}$ .



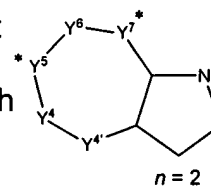
XVI. **Claims 1-10**, drawn to compounds and compositions of Formula I,

wherein the variables outlined in Claim 1 are as described except

for the following requirements:  $n = 2$ ;  $Y^{4'}$ ,  $Y^4$ ,  $Y^5$ ,  $Y^6$ , &  $Y^7$  are each

$C(R^{10})R^{10w}$  or  $Y^7$  and  $Y^5$  may be selected from O, S, S(O), S(O)<sub>2</sub>,

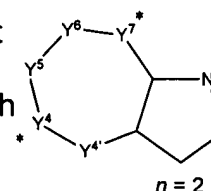
and NR<sup>5</sup> and  $Y^{4'}$ ,  $Y^4$  and  $Y^6$  are each  $C(R^{10})R^{10w}$ .



XVII. **Claims 1-10**, drawn to compounds and compositions of Formula I,

wherein the variables outlined in Claim 1 are as described except

for the following requirements:  $n = 2$ ;  $Y^{4'}$ ,  $Y^4$ ,  $Y^5$ ,  $Y^6$ , &  $Y^7$  are each

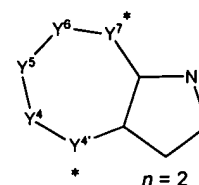


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$C(R^{10})R^{10w}$  or  $Y^7$  and  $Y^4$  may be selected from O, S, S(O), S(O)<sub>2</sub>,  
and  $NR^5$  and  $Y^{4'}$ ,  $Y^5$  and  $Y^6$  are each  $C(R^{10})R^{10w}$ .

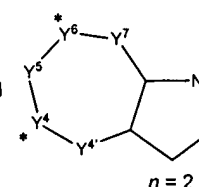
XVIII. **Claims 1-10**, drawn to compounds and compositions of Formula I,

wherein the variables outlined in Claim 1 are as described except  
for the following requirements:  $n = 2$ ;  $Y^{4'}$ ,  $Y^4$ ,  $Y^5$ ,  $Y^6$ , &  $Y^7$  are each  
 $C(R^{10})R^{10w}$  or  $Y^7$  and  $Y^{4'}$  may be selected from O, S, S(O), S(O)<sub>2</sub>,  
and  $NR^5$  and  $Y^4$ ,  $Y^5$  and  $Y^6$  are each  $C(R^{10})R^{10w}$ .



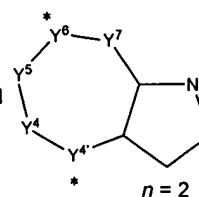
XIX. **Claims 1-10**, drawn to compounds and compositions of Formula I,

wherein the variables outlined in Claim 1 are as described except  
for the following requirements:  $n = 2$ ;  $Y^{4'}$ ,  $Y^4$ ,  $Y^5$ ,  $Y^6$ , &  $Y^7$  are each  
 $C(R^{10})R^{10w}$  or  $Y^6$  and  $Y^4$  may be selected from O, S, S(O), S(O)<sub>2</sub>,  
and  $NR^5$  and  $Y^{4'}$ ,  $Y^5$  and  $Y^7$  are each  $C(R^{10})R^{10w}$ .



XX. **Claims 1-10**, drawn to compounds and compositions of Formula I,

wherein the variables outlined in Claim 1 are as described except  
for the following requirements:  $n = 2$ ;  $Y^{4'}$ ,  $Y^4$ ,  $Y^5$ ,  $Y^6$ , &  $Y^7$  are each  
 $C(R^{10})R^{10w}$  or  $Y^6$  and  $Y^{4'}$  may be selected from O, S, S(O), S(O)<sub>2</sub>,  
and  $NR^5$  and  $Y^4$ ,  $Y^5$  and  $Y^7$  are each  $C(R^{10})R^{10w}$ .





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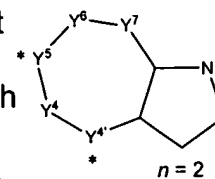
XXI. **Claims 1-10**, drawn to compounds and compositions of Formula I,

wherein the variables outlined in Claim 1 are as described except

for the following requirements:  $n = 2$ ;  $Y^{4'}$ ,  $Y^4$ ,  $Y^5$ ,  $Y^6$ , &  $Y^7$  are each

$C(R^{10})R^{10w}$  or  $Y^5$  and  $Y^{4'}$  may be selected from O, S, S(O), S(O)<sub>2</sub>,

and  $NR^5$  and  $Y^4$ ,  $Y^6$  and  $Y^7$  are each  $C(R^{10})R^{10w}$ .



XXII. **Claims 11-12**, drawn to methods of using the compounds and compositions of Formula I.

**In addition to an election of one of the above Groups, restriction is further required under 35 U.S.C. 121 as follows:** In accordance with the decisions of *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other members obvious under 35 U.S.C. 103.

**Where an election of any one of Groups I-XXII is made, an election of a single compound is further required** including an exact definition of each substituent

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on the base compound, wherein a single member at each substituent group or moiety is selected; *therefore the applicant must select a single specific embodiment of Formula I.*

In the instant case, upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope of the above-identified Group that the elected compound falls within (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). Examination will then proceed on the elected compound AND the entire scope of the invention encompassing the elected species, as defined by the above Groups and common classification. A clear statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first action on the merits. Note that the restriction requirement will not be made final until such time as applicant is informed of the full scope of compounds along with (if appropriate) the process of using or making said compounds under examination. This will be set forth by reference to specific class(es) and subclass(es) examined. *Should applicant traverse on the ground that the compounds are not patentably distinct, applicant should submit evidence now of record showing the compounds to be obvious variants or clearly admit on the record that this is the case.* In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other.

All compounds falling outside the class(es) and subclass(es) of the selected compound and other compounds encompassed by the elected Group above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. (The provisions of 35 U.S.C. 121 applies with regard to double patenting covering divisional applications).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP 608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

### ***Rationale Establishing Patentable Distinctiveness Within Each Group***

Each of **Groups I-XXI** listed above is directed to or involves the use of compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP 806.04, MPEP 808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over either of

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the other inventions (Groups), i.e. they are patentable over each other. Chemical structures that are similar are presumed to function similarly, whereas chemical that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holdings of *Applications of Papesch*, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and *In re Lulu*, 223 USPQ 1257 (Fed. Cir, 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

In the instant application, each of the **Groups I-XXI** represent a subset of Formula I, outlined in Claim 1, wherein the variability of the molecular core is affected. **Groups I-IV** represent compounds with a 5-membered-5-membered-bicyclic structural core ( $n = 0$ ), **Groups V-X** represent compounds with a 6-membered-5-membered-bicyclic structural core ( $n = 1$ ), and **Groups XI-XXI** represent compounds with a 7-membered-5-membered-bicyclic core ( $n = 2$ ). The three types of Groups have distinctive structural cores (i.e. the size of the ring) such that a compound found in the prior art that anticipates the limitations according to Claim 1 for one core would not anticipate the other structural cores. In addition, distinctiveness exists within **Groups I-XXI** such that the compounds within each group would be classified in different Classes and Subclasses.

Furthermore, each of **Groups I-XXI** listed above is directed to compounds which are distinct from each other because of the introduction of a heteroatom into the structural core. The position of two or three heteroatoms within a fused bicyclic core affects not only the classification of those compounds, but again signifies distinctiveness such that a compound found in the prior art that anticipates the limitations according to one core would not anticipate the other structural cores.

***The above Groups represent general areas wherein the inventions are independent and distinct, each from the other because of the following reasons:***

**Groups I-XXI** and **XXII** are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the product ("11. A method of treating joint cartilage damage, osteoarthritis, rheumatoid arthritis or joint inflammation, or alleviating joint pain . . .") can be practiced with other materially different products such as Tylenol or other known anti-inflammatory drugs such as Alleve.

Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application. Each of the **Groups I-XXI** contains a different structural core that requires a different search, whether searching by structure or Class/Subclass and whether using a commercial databases such as STN – Registry/CAPLUS or an internal PTO database.

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Because these inventions are distinct for the reasons given above and the search required for each of the **Groups I-XXII** is not required for another, the restriction for examination purposes set forth as indicated is proper.

### ***Advisory of a Rejoinder***

The following is a recitation of MPEP 821.04, Rejoinder:

Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. § 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02(c) and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims, which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product by way of amendment pursuant to 37 CFR 1.121. In view of the rejoinder procedure, and in order to expedite prosecution, applicants are encouraged to present such process claims, preferably as dependent claims, in the application at an early stage of prosecution. Process claims which depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance. Amendments submitted after final rejection are governed by 37 CFR 1.116. Process claims which do not depend from or otherwise include the limitations of the patentable product will be withdrawn from consideration, via an election by original presentation (see MPEP § 821.03). Amendments submitted after allowance are governed by 37 CFR 1.312. Process claims which depend from or otherwise include all the limitations of an allowed product claim and which meet the requirements of 35 U.S.C. 101, 102, 103, and 112 may be entered.

Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either: (A) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2); or (B) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2) even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26(a) states that "[T]he Commissioner may refund any fee paid by mistake or in excess of that required. A change of purpose after the payment of a fee...will not entitle a party to a refund of such fee..." In this case, the fees paid under 37 CFR 1.129(b) were not paid by mistake nor paid in excess, therefore, applicant would not be entitled to a refund.

In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application

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containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. 103(b)" (1184 TMOG 86(March 26, 1996)):

"However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all of the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

Therefore, in accordance with MPEP 821.04 and *In re Ochiai*, 71 F. 3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

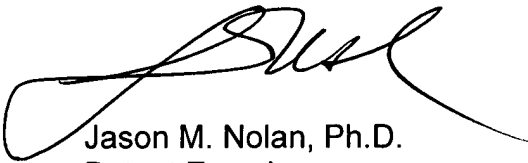
### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason M. Nolan, Ph.D. whose telephone number is (571) 272-4356. The examiner can normally be reached on Mon - Fri (9:00 - 5:30PM).

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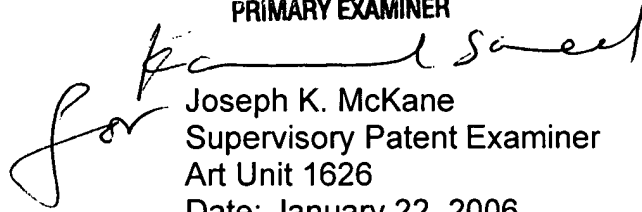
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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